

**REMARKS**

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

Claims 1-42 are currently pending. Claims 1, 2, 3, 8, 10, 11, 13-18, 23-26, 30, 31, 34-40 and 42 are amended herein. Independent claims 1 and 24 are amended to recite that the biodegradable polymer is a homo- or copolymer prepared from  $\alpha$ -hydroxy acids or cyclic dimers of  $\alpha$ -hydroxy acids or a combination thereof. Claims 1, 2, 3, 8, 10, 11, 13-18, 23, 25, 26, 30, 31, 34-40 and 42 are amended to place the claims in more proper U.S. format, *i.e.*, to recite proper Markush groups and to remove reference to alternative subject matter. The alternative subject matter amended herein from the claims has been made the subject of new claims 45-76, added herein. Basis for these amendments and new claims may be found throughout the specification and claims as-filed, especially at page 2, lines 8-12 and page 5, lines 24-32. Thus, no prohibited new matter has been introduced by way of this Amendment. Applicants reserve the right to pursue in a division or continuation application any subject matter canceled by way of this Amendment without prejudice or disclaimer.

The following table indicates the basis for each new claim.

New Claim	Basis found in claims as-filed
45	8

New Claim	Basis found in claims as-filed
46	10
47	11
48	12
49	12
50	13
51	16
52	17
53	17
54	17
55	18
56	25
57	25
58	25
59	26
60	31
61	34
62	35
63	38
64	39
65	39
66	39
67	40
68	42
69	2

New Claim	Basis found in claims as-filed
70	2
71	2
72	3
73	1
74	1
75	24
76	24

**Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 1-42 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention. The Office Action states that the phrase "wherein the biodegradable polymer can be dissolved in an organic solvent..." was not supported by the original specification. In the interest of expediting prosecution, this phrase has been removed from the claims by way of the present Amendment. Thus, this rejection is obviated.

**Rejections under 35 U.S.C. § 103**

Claims 1-42 stand rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Tice *et al.* (U.S. Patent No. 5,407,609), further in view of Ekman *et al.* (U.S. Patent No. 4,822,535).

Tice *et al.* is cited for purportedly disclosing methods for microencapsulating an agent to form a microencapsulated product. In preparation, a polymer is first dissolved in a solvent. The solvent can purportedly be selected from a variety of common organic solvents. The active substances are then added to the solvent containing the polymer. The Office Action states that the motivation to utilize propylene glycol as the continuous phase in the invention of Tice *et al.* is provided by Ekman *et al.*, which purportedly disclose that polyethylene glycol is a preferred phase in comparison to standard organic solvents when making microparticles. Applicants respectfully traverse.

In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See* M.P.E.P. §2142. Applicants respectfully submit that these criteria have not been met in the present Office Action.

Before turning to the specific rejection, Applicants note that independent claims 1 and 24 are amended herein to recite that the biodegradable polymer is homo- or copolymers prepared from  $\alpha$ -hydroxy acids or cyclic dimers of  $\alpha$ -hydroxy acids or a combination thereof, *i.e.*, poly(lactide-co-glycolide) (PLGA). As further set forth in the present specification on page 2, lines 8-12 and page 5, lines 24-32, PLGA is a well established polymer for preparing sustained release microspheres and often the first choice for preparing biocompatible microspheres intended for parenteral administration in humans, and

thus its characteristics are well known to the skilled artisan. However, PLGA and related polymers, of the group aliphatic polyesters, are not soluble in water.

To this end, Applicants submit that the polymer of the present invention is dissolved in an organic solvent. Specifically, the first step in the process to form the microspheres is dissolving the polymer in an organic solvent. Specifically, a process for the preparation of microspheres from polymers soluble in water has been used in the art. Two mutually immiscible aqueous liquid phases are used, of which one is solidified into microspheres. However, these methods cannot be used for preparation of microspheres from polymers that cannot be dissolved in water.

Turning now to the cited references, Applicants submit that Ekman *et al.* merely disclose the preparation of microparticles from polymers that can be dissolved in water. This reference discloses the use of an aqueous two-phase system. Such a system cannot exist if the polymer used to form the microparticles is dissolved in an organic solvent. There is no motivation from Ekman *et al.* to use a solution of PEG as the outer phase when preparing microspheres from a polymer that is dissolved in an organic solvent. Thus, this reference fails to remedy the deficiencies of Tice *et al.*

In light of these remarks and the amendments to claims 1 and 24 made herein, Applicants submit that the cited references, alone or in combination, fail to suggest the modification of the references, fail to provide a reasonable expectation of success, and fail to disclose or suggest all of the claim limitations. As the present claims recite polymers that are not soluble in water (only soluble in an organic solvent), the cited references are not

applicable to the present invention. Thus, Applicants request that this rejection be withdrawn.

**CONCLUSION**

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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